REMARKS

Claims 1-3, 6-15 and 28-33 are pending, wherein claims 1, 2, 7, 14, 28 and 29 have been amended. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

The Office Action rejects claims 1-3, 6-10, 14-15 and 28-33 under 35 U.S.C. § 112, first paragraph, on the grounds that they fail to comply with the written description requirement. In particular, the Office Action objects to the use of the terms "initially a non-adhesive covering", "a continuous outer cover", and "to completely encapsulate and retain" in claims 1, 14 and 28. In response, Applicant submits that the foregoing terms are inherent in the application as originally filed and were merely added to emphasize such inherent features. Nevertheless, in an effort to advance prosecution, the forgoing terms have been removed from the claims. Nevertheless, Applicant submits that a dry, hydrophilic and gelatinizable material will inherently be non-adhesive prior to being wetted with water or blood, that the covering shown in Figures 1A, 1B and 1C is "continuous" except perhaps for tiny spaces between the individual threads of the knitted or woven fabric, and that the covering shown in these figures completely encapsulates and retains the bone growth promoting material within the defined space. The term "completely encapsulate" is really no different than the term "encapsulate". They both mean the same thing except that the term "completely" adds emphasis. As taught at page 8, paragraph [0023], of the specification, the delivery system includes "a covering around at least a portion of a bone growth promoting material". The term "around at least a portion" implies that it may surround all of the bone growth promoting material. A covering that surrounds all of the bone growth promoting material can be a continuous covering that completely encapsulates the bone growth promoting material. In any event, Applicant has amended the claims to remove the above-identified terms.

The Office Action rejects claims 1-3, 6-10, 14-15 and 28-33 under 35 U.S.C. § 103(a) as being unpatentable under Tormala et al. (US 4,863,472) taken with Silverberg (US 4,755,184), Levy (US 5,292,253), and Vyakarnam et al. (US 6,306,424), and further in view of Kenyon et al. (US 2,423,707). In response, Applicant submits that the teachings of the combined references, when considered in their entirety as required by *Graham v. John Deere Co.*, neither teach nor suggest the combination of elements recited in the claims.

In rejecting claim 1, the Office Action combines Tormala et al., Silverberg and Kenyon. These references, when considered as a whole, including teachings that lead away from the invention, do not teach or suggest the combination of elements recited in claim 1 as now

presented, which claims a moisture activated implant device for promoting bone growth in the void space comprising a dry covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue, wherein the dry covering consists essentially of oxidized cellulose and a bone growth promoting material disposed within the enclosed space defined by the dry covering, wherein the dry covering encapsulates and retains the bone growth promoting material within the enclosed space prior to use.

Tormala et al. is the primary reference and discloses an implant device that allegedly includes a covering comprised of a "water absorbing gelatinizable material" that encapsulates a bone growth material. The device of Tormala et al. includes "a supporting structure" made from one of the polymeric materials listed in Tables 1 and 2, all of which are hydrophobic, yet resorbable, polymer materials that are slowly replaced over time with bone tissue. Col. 2, lines 60-68; col. 3, lines 3-4, 28-68; col. 4, lines 1-2, 52-57; col. 7, lines 39-68; col. 8, lines 1-7. According to Tormala et al., an important feature of the "supporting structure" is the inclusion of at least one orifice "whose size is bigger than the size of pores of the supporting structure and bigger than the size of the bone graft powder particles", which is necessary to permit the bone to grow within the supporting structure over time. Col. 2, lines 44-50; Figs. 1, 2(a), 2(b), 2(c), 2(d) and 2(e). In the embodiment shown Fig 2(f), the orifice in the bottom of the chute is initially covered with a rapidly resorbable polymeric material. Col. 6, lines 20-24. In other embodiments, the enlarged orifice can be initially covered with a thin ceramic plate. Col. 3, lines 10-12. Other materials that can be used "*in addition to*" the polymers listed in Table 1 include collagen, Kargut, chitine, gelatine and cellulose derivatives. Col. 4, lines 17-24. In every example of Tormala et al., the supporting structure persisted for several weeks while the bone began to grown into the supporting structure. Apart from the rapidly resorbable film used to cover the enlarged orifice of the supporting structure, Tormala et al. neither teaches nor suggests the use of hydrophilic materials that can react with water. Thus, while part of the supporting structure might react with water, Tormala et al. neither teaches nor suggests a device in which the entire outer covering reacts with water to form a sticky, gelatinous material.

As now presented, claim 1 defines a device in which the outer covering "consists essentially of oxidized cellulose". Tormala et al. neither teaches nor suggests any such device, as the vast majority of the supporting structure consists of one of the polymers listed in Tables 1

and 2 notwithstanding the optional use of other materials that are less hydrophobic (*e.g.*, to form an "inner support structure" as disclosed at the bottom of column 4).

Moreover, Tormala et al. neither teaches nor suggests an outer covering that consists essentially of oxidized cellulose and encapsulates a bone growth promoting material. None of the materials disclosed in Tormala et al. comprise oxidized cellulose. Moreover, the rapidly resorbable covering for the enlarged orifine may possibly form a gelatinous material when exposed to water but it does not "encapsulate" (*i.e.*, surround and encase) the bone growth material. Tormala et al. emphasizes the criticality of the enlarged orifice by distinguishing over prior art devices that completely enclose the bone growth promoting material and do not include the enlarged orifice. Tormala et al. teaches that "[p]orous, flexible casings, which have been manufactured e.g. of collagen or of resorbable (in tissue degradable) polymer, into which casings the bone graft powder is closed, separate, ... the bone graft particles and bone tissue surface from each other." Col. 2, lines 16-20. This prevents growth of the bone tissue into the graft particles. Col. 2, lines 20-24. That suggests that collagen and other similar resorbable materials do not form a sticky, gelatinous material when exposed to water. Otherwise, Tormala et al. would not have taught that such materials prevent contact between bone and bone growth particles during use. Therefore, just because a material is described as being "resorbable" does not mean that it is a hydrophilic material that becomes gelatinizable upon contact with water or blood.

Silverberg is similarly deficient in failing to teach or suggest an implant device that includes a dry covering made from oxidized cellulose in order to become sticky and gelatinous when contacted with water. Silverberg discloses a casing made from polyglycolide, a known hydrophobic polymer, collagen or cellulose. Polyglycolide is one of the materials listed in Table 1 of Tormala et al. Moreover, according to Tormala et al., flexible casings made of collagen prevent contact between the bone growth promoting material and the bone. Tormala et al., col. 2, lines 16-24. That clearly indicates that "collagen", as disclosed in Silverberg, is not a water absorbing gelatinizable material that becomes sticky and gelatinous upon contact with water. Otherwise, casings made from "collagen" would not prevent contact between bone and bone growth material. Consistent with properties of polyglycolide and collagen, it is clear that the term "cellulose" in Silverberg is also not a hydrophilic water absorbing polymer that becomes gelatinous upon contact with water. Cotton gauze is a type of cellulous material that does not become gelatinous upon contact with mater. Indeed, cotton is a common form of cellulose used to form clothing, which can be laundered without becoming gelatinous and sticky. Moreover,

the teaching in Silverberg that the casing can be made from either polyglycolide, collagen or cellulose appears to teach away from the use of water gelatinizable materials, which would not perform as intended by Silverberg. Accordingly, even if one were to combine Tormala et al. and Silverberg, the combined teachings would neither teach nor suggest every limitation recited in claim 1.

Moreover, Tormala et al. disparages devices like those disclosed in Silverberg that completely encapsulate the bone growth promoting material rather than providing an enlarged orifice for which bone tissue can grow inside the supporting structure. Tormala et al. teaches that porous flexible casings made of collagen or other resorbable polymers such as those disclosed in Silverberg, which do not include an enlarged orifice, prevent growth of bone into the bone growth promoting particles. Col. 2, lines 16-24. As a result, Tormala et al. teaches a way from the device of Silverberg in which the sheath encapsulates the bone growth material rather than providing an enlarged orifice through which bone can grow. Because of this clear teaching away, there is no teaching, suggestion or other reason why one of skill in the art would have been combined Tormala et al. and Silverberg to arrive at the claimed invention.

Finally, the Office Action acknowledges that neither Tormala et al. nor Silverberg discloses a dry covering that is gelatinizable in water and that becomes sticky and adhesive upon contact with water. For that reason, the Office Action cites to Kenyon which merely discloses a gelatinizable gauze made of oxidized cellulous. The Office Action, however, fails to state a valid reason why one of skill in the art would have modified Tormala et al. and Silverberg to include the gelatinizable gauze of Kenyon. It is clear that Kenyon only discloses gelatinizable gauze for use in arresting bleeding caused by flesh wounds, not a delivery device for insertion into a bone defect that includes a bone growth material and a covering that encapsulates the bone growth material, wherein the covering helps hold the bone growth material together so as to not fall out of the bone defect during use. Kenyon has nothing at all to do with repairing bone defects but only the stoppage of bleeding. In sharp contrast, the claimed invention has little or nothing to do with stopping bleeding but rather providing a bone growth promoting material within a bone defect to provide a solid bone-compatible scaffolding that favors bone growth rather than epithelial growth.

Accordingly, there is no teaching, suggestion, motivation or other reason as to why one of skill in the art would have modified Tormala et al. and Silverberg to include the Kenyon material. Moreover, the material disclosed in Kenyon would not be useful in forming the

supporting structure of Tormala et al., a critical feature of which is that this supporting structure must persist for sufficient time so that "the bone tissue grows inside of the supporting structure from the orifice" as plainly taught in Tormala et al. Col. 2, lines 60-61. The same is true for the Silverberg device, which is designed to persist for weeks while bone grows through the covering. Col. 6, line 10 – col. 9, line 47. In all cases, the outer mesh casing of Silverberg was detectable after 2 weeks in the body. *Id.* In contrast to both Tormala et al. and Silverberg, the gelatinizable gauze of Kenyon gelatinizes and therefore disintegrates as a distinct structure upon contact with water or blood in order to seal the wound. Moreover, Silverberg teaches that "the implant is typically wetted with sterile saline solution prior to installation to facilitate lubrication and plasticity." Col. 4, lines 13-15. Kenyon in contrast discloses a gelatinizable gauze that becomes sticky upon contact with water in order to seal the wound. Forming an implant device that becomes sticky upon contact with water would not permit the Silverberg device to be used as intended (*i.e.*, injected through a syringe using water as a "lubricant").

The recent decision of *KSR v. Teleflex* and the subsequent examination guidelines issued by the USPTO in response to *KSR* both require an obviousness rejection to clearly state a valid reason as to why one of skill in the art would have combined references in order to arrive at the claimed invention. It is not sufficient to merely show that all elements are independently shown in the art. Moreover, *KSR* cites to the *Adams* case, in which the Supreme Court states that it is not obvious as a matter of law to do that which the prior art teaches away from. Tormala et al. teaches away from an implant device in which the support structure "encapsulates" a bone growth promoting material rather than providing an enlarged orifice through which bone can grow during the useful life of the implant. Thus Tormala et al. plainly teaches away from an implant device that does not include an enlarged orifice. Providing an enlarged orifice does not encapsulate the granules but would permit them to fall through the orifice. Accordingly, according to *Adams* and *KSR*, the claims of the invention are unobvious over Tormala et al. as Tormala et al. teaches away from the device of claim 1, which requires a dry covering that encapsulates (*i.e.*, completely encases and surrounds) the bone growth promoting material. Moreover, because the dry covering consists essentially of oxidized cellulose, there are no regions that will more quickly disintegrate away and form an enlarged orifice, as taught in Tormala et al.

The remaining references were cited to teach specific features of the dependent claims and do not remedy the deficiencies of Tormala et al., Silverberg and Kenyon as noted above. Accordingly, claim 1 as now presented is believed to be unobvious over the applied art.

Dependent claims 2-3, 6-10 and 14-15 are patentable for at least those reasons for why claim 1 is patentable and include additional limitations that may further distinguish over the art of record. For example, claim 2 defines an implant device that "consists essentially of oxidized cellulose and the bone growth promoting material", thereby excluding hydrophilic polymers such as polylactic acid or others listed in Table 1 which make up the majority of the Tormala et al. supporting structure. It also distinguishes over the sheath materials disclosed in Silverman (*i.e.*, polyglycolide, collagen and cellulose). Finally, it emphasizes a structural relationship between the oxidized cellulose and the bone growth promoting material that is not found in Kenyon, which has absolutely nothing at all to do with bone growth promoting implant devices and is therefore not logically relevant to the claimed invention.

Claim 7 further claims a device having a "non-elongate pillow-like configuration" (*e.g.*, as illustrated in Figure 1B), which is neither taught nor suggested in any of the cited references (*i.e.*, all devices disclosed in Tormala et al. (Figs. 1 and 2(a)-2(f)) and Silverberg (Fig. 1) are elongate structures with a length that is several times the width).

Claim 8 further claims a both growth promoting device that is stored within moisture-resistant packaging prior to use to prevent premature gelatinization of the dry covering. Because the outer coverings of Tormala et al. and Silverberg are not manifesting water-gelatinizable, there is no teaching, suggestion, motivation or other reason why one of skill in the art would have combined these references with Vyakarnam, which has nothing at all to do with bone growth promoting implants but rather gelatinous foam dressings.

Claims 9 and 10 further claim an adhesive mixed within the bone growth promoting material. None of the cited references disclose or suggest a device having a dry covering that is water-gelatinizable and which consists essentially of oxidized cellulose in combination with an adhesive dispersed with the bone growth promoting material.

Claim 14 recites specific method steps that are neither taught nor suggested in the applied art. For example, claim 14 requires that, upon placing the device is adjacent to bone tissue, the covering becomes gelatinous upon contact with water in order to maintain the bone growth promoting material adjacent to bone tissue. In contrast, neither Tormala et al. nor Silverberg disclose or suggest a method in which the implant device becomes gelatinous upon contact with

water in order to maintain the bone growth promoting material adjacent to bone tissue. Instead, a resorbable hydrophobic polymer such as polyglycolide merely maintains a shell around the bone growth material until bone has grown into the shell. Thereafter, the resorbable shell material is slowly resorbed over time as it is replaced with bone. Moreover, as the wound dressing in Kenyon is not used in connection with any bone growth material, Kenyon fails to disclose or suggest a method in which the wound dressing maintains a bone growth promoting material adjacent to bone tissue. Accordingly, the combined teachings of Tormala et al., Silverberg and Kenyon fail to disclose every element recited in claim 14 such that claim 14 is not *prima facie* obvious over these references. Claim 15 is likewise patentable over the art of record.

Claim 28 is similar to claim 1 but further claims a thickener dispersed among the bone growth promoting material that forms a viscous gel or firm putty upon contact with water. Tormala et al. does not disclose any such device. Instead, Tormala et al. discloses an embodiment in which resorbable polymer fibers are melted together while forming the implant device in order to bind the bone growth particles together. "Such a material can be manufactured for example by mixing ceramic powder with resorbable polymer and by *melting or sintering the mixture to a solid sample*". Col. 5, lines 3-6 (emphasis added). Tormala et al. does not disclose or suggest any embodiments that include "a thickener dispersed among the bone growth promoting material that forms a viscous gel or firm putty upon contact with water" as recited in claim 28. Accordingly, claim 28 is clearly patentable over Tormala et al. The Office Action fails to identify any other reference that allegedly contains such teachings. Similar to Tormala et al., Levy discloses the use of proteins that are heat melted together to bind calcium-containing particles together. Col. 3., lines 19-26; col. 4, lines 13-25. Like Tormala et al., Levy neither teaches nor suggests a device constructed so that a thickener (*e.g.*, which is an initially dry, chopped or powdered material) forms a viscous gel or firm putty upon contact with water, as required by claim 28. Accordingly, claim 28 is not *prima facie* obvious over any combination of references identified in the Office Action.

Claims 29-33 are similarly patentable over the art of record and further recited additional elements that further distinguish over the art of record. For example, claim 29 further specifies that the implant device consists essentially of oxidized cellulose, the bone growth promoting material, and the thickener. None of the applied, either alone or in combination, disclose or suggest the specific combination of elements recited in claim 29. Tormala et al. discloses a supporting structure that at least includes one of the hydrophobic polymers in Table 1 and

optionally one of the other more hydrophilic, resorbable materials disclosed elsewhere. The covering of Tormala et al. does not consist essentially of oxidized cellulose in any other similar water-gelatinizable material. Accordingly, when one of skill in the art starts with Tormala et al. as the primary reference, there is no teaching, suggestion, motivation or other reason to essentially replace the polymers of Table 1 with oxidized cellulose as in claim 20.

Claim 30 further specifies that "the thickener comprises at least one of gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, ground catgut, or powdered catgut". In contrast, Tormala et al. merely discloses the use of unnamed resorbable polymer fibers that can be melted or sintered to form a solid ceramic structure. *See* col. 3, lines 1-2; col. 4, lines 65-69; col. 5, lines 1-6. Levy discloses fibrin or collagen but none of the materials recited in claim 30.

Claim 31 further specifies that "the thickener comprises a biocompatible gelatinous collagen material", which is neither taught nor suggested in Tormala et al. or any other reference as a thickener that can be used to bind the particles together upon contact with water (*e.g.*, Levy discloses heat melting of collagen).

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 3rd day of September 2008.

Respectfully submitted,

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